UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

Civil Action No. _____

MECKLENBURG COUNTY,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AND AMERISOURCEBERGEN DRUG CORPORATION,

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Mecklenburg County, by and through the undersigned attorneys, for their Complaint against the named Defendants seeking to recover its damages as a result of the opioid epidemic Defendants caused, allege as follows:

Introduction

1. Opioid addiction and overdose in the United States as a result of prescription opioid use has reached epidemic levels over the past decade.

2. While Americans represent only 4.6% of the world's population, they consume over 80% of the world's opioids.

3. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.[1] In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).[2]

4. By 2014, nearly two million Americans either abused or were dependent on opioids.[3]

5. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[4]

6. The statistics tell a grim story. More than 40 people die every day from overdoses involving prescription opioids. Since 1999, at least 200,000 people in the United States have died from overdoses related to prescription opioids.

7. The Centers for Disease Control reports that overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths.

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[1] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed August 18, 2017) (internal footnotes omitted).

[2] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States*, 2000-2010, 51(10) Med. Care 870-78 (2013).

[3] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: http://www.cdc.gov/drugoverdose/opioids/prescribed.html (as viewed May 10, 2016).

[4] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed August 18, 2017).

8. While the prescriptions have quadrupled, there has not been an overall change in the amount of pain that Americans reported. With no apparent material impact on pain, however, people are dying from opioids in the United States every day (over 60% of drug overdose deaths now involve an opioid). From 2000 to 2015 more than half a million people died from drug overdoses (including prescription opioids and heroin). The most recent figures from the Centers for Disease Control suggest that 145 Americans die every day from an opioid overdose (prescription and heroin).

9. Overdose deaths, however, are just the most visible consequence of an ever-growing opioid addiction crisis. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[5] In 2015, an estimated 2,000,000 Americans aged twelve or older had a substance use disorder involving prescription pain relievers. [6]

10. Among long-term opioid users, between 30% and 40% experience problems with opioid use disorders.[7]

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[5] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[6] American Society of Addition Medicine, Opioid Addiction 2016 Facts & Figures (available at https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf) (last visited October 27, 2017).

[7] J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) Addiction 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011). One-third of Americans who have taken prescription opioids for at least two months say they became addicted to, or physically dependent on them. Available at https://www.washingtonpost.com/national/health-science/one-third-of-long-term-users-say-theyre-hooked-on-prescription-opioids/2016/12/09/e048d322-baed-11e6-91ee-1adddfe36cbe_story.htm?utm_term=.7259d7ee60b4 (viewed September 27, 2017).

11. Many addicts, finding painkillers too expensive or too difficult to obtain, have turned to heroin. According to the American Society of Addiction Medicine, four out of five people who try heroin today started with prescription painkillers.[8]

12. County governments and the services they provide their citizens have been strained to the breaking point by this public health crisis.

13. North Carolina and Mecklenburg County are in the midst of this crisis. Their statistics mirror the national statistics.

14. In North Carolina, opioid-related overdose deaths increased by over 800% between 1999 and 2016. There were 1,194 unintentional opioid-related deaths in 2016, up from 1,110 deaths in 2015.

15. In 2015, at least 61 people died from opiate overdoses in Mecklenburg County, more than doubling the 26 people that died ten years before in 2005.[9] In 2016, 112 people died from opioid related death, nearly doubling the number of deaths just one year before.[10]

16. Emergency room visits related to opioid overdoses has also increased in Mecklenburg County going from 263 in 2015 to 340 in 2016.[11]

17. The dramatic increase in prescription opioid use over the last two decades, and the resultant public-health crisis, is no accident.

18. This suit takes aim at two primary causes of the opioid crisis as it exists in Mecklenburg County.

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[8] Opioid Addiction 2016 Facts & Figures, American Society of Addiction Medicine, Available at: https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

[9] https://governor.nc.gov/news/county-county-figures-opioid-crisis-north-carolina.

[10] http://www.wsoctv.com/news/local/opioid-usage-skyrocketing-in-mecklenburg-county/623352711

[11] www.charlotteagenda.com/97526/opioid-related-deaths-mecklenburg-county-climbing-efforts-underway-prevent/.

19. First, the crisis was precipitated by many of the Defendants named herein who manufacture, sell, and/or market and promote prescription opioid painkillers ("Manufacturers" or "Manufacturer Defendants") and who, through nefarious and deceptive means and using one of the biggest pharmaceutical marketing campaigns in history, carefully engineered and continue to support a dramatic shift in the culture of prescribing opioids by falsely portraying both the risks of addiction and abuse and the safety and benefits of long-term use.

20. Manufacturers' goal was simple: to dramatically increase sales by convincing doctors that it was safe and efficacious to prescribe opioids to treat not only the kind of severe and short-term pain associated with surgery or cancer, but also for a seemingly unlimited array of less severe, longer-term pain, such as back pain and arthritis to name but two examples.

21. Manufacturers knew, however, that their opioid products were addictive, subject to abuse, and not safe or efficacious for long-term use.

22. Manufacturers' nefarious plan worked and they dramatically increased their sales and reaped billions upon billions of dollars of profit at the expense of millions of people who are now addicted and the thousands who have died as a result. In 2012 alone, opioids generated $8 billion in revenue for drug companies. Of that amount, $3.1 billion went to Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately $9.6 billion.[12]

23. The National Institutes of Health ("NIH") identifies Defendants' "aggressive marketing" as a major cause of the opioid epidemic in this country: "Several

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[12] D. Crow, *Drugmakers hooked on $10bn opioid habit*, Financial Times (August 10, 2016). In 2015, the Sackler family, the Purdue company's sole owners, appeared at number sixteen on Forbes magazines's list of America's richest families. Available at https://www.firstthings.com/article/2017/03/american-carnage (as viewed September 27, 2017).

factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[13] (emphasis added.) As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes" are not really independent causative factors but are, in fact, the direct result of "the aggressive marketing by pharmaceutical companies."

24. Second, the crisis was also precipitated by the three pharmaceutical distributor Defendants, Cardinal Health, Inc., AmerisourceBergen Corp., and McKesson Corporation (hereinafter "Distributors" or "Distributor Defendants") who have failed to maintain effective controls over the distribution of prescription opioids thereby contributing to the oversupply of prescription opioids, fueling an illegal secondary market.

25. Among other things, pharmaceutical distributors fail to identify suspicious orders of opioids, fulfilling such orders rather than refusing and reporting them to legal authorities as provided under applicable laws and regulations.

26. The Distributor Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids within the County than they know are necessary for legitimate medical uses, and by failing to report obviously suspicious orders through which enormous quantities of opioids are being diverted to pill mills. As millions became addicted to opioids, "pill mills" often styled as "pain clinics" sprouted nationwide, including within the County. These pill mills,

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[13] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed August 18, 2017) (emphasis added).

typically under the auspices of licensed medical professionals, operate criminally to sell high volumes of prescription opioids under the guise of medical treatment when, in fact, they were knowingly fueling and profiting from the crisis by providing an endless supply of opioids for non-medical purposes to a drug-addicted population.

27. Prescription opioid pill mills cannot operate effectively without the tacit support and blind eye of the Distributors.

28. Not coincidentally, the overdose death rate, substance use disorder treatment admissions and the devastating burden on state and local government and the services they provide increased in parallel with Manufacturers' aggressive false marketing campaign, Distributors' failure to control, and the resultant dramatic increase in sales of opioids. Indeed, sales of prescription opioids quadrupled between 1999 and 2010, the overdose death rate also quadrupled since 1999 and the substance use disorder treatment admission increased six-fold between 1999 and 2009.[14]

29. The crisis Defendants caused has directly impacted Mecklenburg County as it bears the financial brunt of this epidemic as it unfolds in the County.

30. Apart from (and because of) the toll on human life, the crisis has financially strained the services Mecklenburg County provides its residents and employees. Human services, social services, court services, law enforcement services, the office of the coroner/medical examiner and health services, including hospital, emergency and ambulatory services, have all been severely impacted by the crisis. For example, as a direct and foreseeable consequence of Defendants' egregious conduct, the County incurred and continues to incur significant costs related to health care stemming from prescription opioid dependency. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, emergency department services, and inpatient hospital services, among others. Defendants' conduct

[14] American Society of Addition Medicine, Opioid Addiction 2016 Facts & Figures.

also caused the County to incur substantial economic, administrative and social costs relating to opioid addiction and abuse, including criminal justice costs, victimization costs, child protective services costs, lost productivity costs, and education and prevention program costs among others.

31. Indeed, Mecklenburg County's medical examiner has even said its morgue needs to add more storage spaces in coolers to handle the increased opioid deaths.[15]

32. Even now, having created a public health crisis, Manufacturers have not pulled their opioid products from the market, acknowledged the very real dangers of addiction and abuse, even if the opioids are taken as prescribed, or acknowledged that opioids are inappropriate for long-term pain management. Instead, Manufacturers have taken the position that their opioid products are not dangerous and continue to sell these dangerous and addictive drugs, thereby continuing to fuel the crisis.

33. Similarly, despite the widespread and highly detectable diversion and misuse of prescription opioids, the Distributors continue to oversupply the County with prescription opioids turning a blind eye to patently suspicious orders. Their oversupply and failure to control distribution or to identify and report suspicious orders fuels the opioid crisis within the County to the present day.

34. By its Complaint, Mecklenburg County seeks to recover from Defendants its damages as a result of the opioid public health crisis Defendants caused.

JURISDICTION AND VENUE

35. This Court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general business within North Carolina, have transacted substantial business with North Carolina entities and residents, and have caused harm in North Carolina as a result of the specific business activities complained of herein.

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15 http://www.wsoctv.com/news/local/morgue-needs-more-space-as-opioid-deaths-increase/646991524

36. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

37. Venue is proper in this district under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Western District of North Carolina.

38. Jurisdiction is proper in the Western District of North Carolina pursuant to 28 U.S.C. § 1332.

PARTIES

39. Plaintiff Mecklenburg County is organized and existing under the laws of the state of North Carolina. Mecklenburg County is located in the southwestern part of the state of North Carolina. It is the most populous county in the state of North Carolina and the first county in the Carolinas to surpass 1 million in population. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

40. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. None of the PPL's partners have citizenship in the State of North Carolina.

41. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

42. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

43. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, in the State of North Carolina and in Mecklenburg County, including the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule[16]
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Byprenorpine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

44. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

45. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were

[16] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual; marketing and selling billions of dollars of opioids each year as if they were safe and efficacious for long-term use.

46. Instead of learning from Purdue's misdeeds, the other named manufacturer Defendants, Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., and Endo Pharmaceuticals, Inc, instead emulated Purdue's false marketing strategy and in turn marketed and sold billions of dollars of prescription opioids as safe and efficacious for long-term use, knowing full well that they were not.

47. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

48. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

49. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in the County, including the following:

Table 2. Cephalon Opioids

Drug Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

50. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in the County.

51. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

52. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

53. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

54. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

55. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

56. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen Pharmaceuticals' profits inure to J&J's benefit.

57. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the County, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta[17]	Tapentadol	Schedule II
Nucynta ER	Tapentadol extended release	Schedule II

58. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

59. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

60. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

61. EHS and EPU (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in the County, including the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

62. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it

[17] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

63. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on postmarketing data in reaching its conclusion based on the concern that the benefits of the drug may no longer outweigh its risk of abuse.[18]

64. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

65. Defendant McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including North Carolina and Mecklenburg County.

66. Defendant McKesson is the largest pharmaceutical distributor in North America. McKesson delivers one-third of all pharmaceuticals used in North America.

67. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

68. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including North Carolina and Mecklenburg County.

69. Cardinal is one of the largest distributors of opioid pain medications, including within including North Carolina and Mecklenburg County.

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[18] FDA requests removal of OPANA ER for risks related to abuse. Available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm (accessed August 17, 2017).

70. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania.

71. Defendant AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including North Carolina and Mecklenburg County.

72. Defendant AmerisourceBergen is one of the largest distributors of opioid pain medications in the country, including within North Carolina and Mecklenburg County.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. The Pain-Relieving and Addictive Properties of Opioids

73. "Opiates" are alkaloids derived from the opium poppy, including opium, heroin, morphine, and codeine. "Opioids" are synthetic or partly-synthetic drugs that are manufactured to work in a similar way to opiates. Opioids act like opiates when taken for pain because they have similar molecules. The products manufactured by Defendants are opioids. The term "opioids" is now commonly used for both natural and synthetic versions, and that term is used herein to refer to both.

74. The pain-relieving properties of opioids have been recognized for millennia. So has the magnitude of their potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

75. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain - particularly on the battlefield - and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United

States,[19] and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

76. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

77. Studies and articles from the 1970s and 1980s also observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

78. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[20]

79. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

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[19] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

[20] R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[21]

(emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[22]

80. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."[23]

81. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for

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[21] R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[22] *Id.*
[23] J. Loeser. Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013)).

months after a complete withdrawal from opioids, depending on how long the opioids were used.

82. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which she has become accustomed – up to and including doses that are "frighteningly high."[24] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

83. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

84. The Manufacturer Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

85. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the

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[24] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med. 1422 (2010).

FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[25] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

86. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[26]

87. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

B. Opioid Therapy Makes Patients Sicker Without Long Term Benefits

88. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

89. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

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[25] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[26] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed August 18, 2017).

90. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[27]

91. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

92. While opioids may work acceptably well for a while, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[28]

93. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

94. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase

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[27] A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

[28] *See* A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, rebound headaches, and reported a lower quality of life than patients taking other medications.

C. Defendants' Scheme to Change Prescriber Habits and Public Perception

95. For the reasons just alleged, the commonly held views amongst doctors was that opioids should only be used short-term and often when the patient is in the hospital – for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care – as the risks of addiction are low or of little significance.

96. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. The Manufacturer Defendants recognized that if they could sell opioids not just for short-term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and profits. Further, they recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

97. The Manufacturer Defendants knew that in order to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. Defendants needed, in other words, to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

98. So Defendants designed a false and deceptive marketing strategy aimed at clinicians whom they desired to prescribe opioids in a way they had never been used before.

99. The Manufacturer Defendants did not set out to change the medical community's view, however, through legitimate scientific research, because scientific

research would not have supported the conclusion Defendants desired (that prescription opioids could be used to treat chronic conditions long-term). Rather, to accomplish their goal of blockbuster profits and dramatically increased sales, Defendants turned to the marketing and PR world to instead create a misperception in the medical community.

100. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy.

101. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, Defendants sought to distort medical and public perception of existing scientific data.

102. As explained more fully herein and illustrated in Exhibit A, the Manufacturer Defendants, collectively and individually, poured vast sums of money into generating articles, creating continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but phony "consensus" supporting the long-term use of opioids.

103. Not only did the Manufacturer Defendants begin to create a phony consensus on the safety and efficacy of using prescription opioids to treat chronic pain, but they also created a new narrative, that doctors were not being responsible to their patients in treating pain if they did not use these new wonder drugs for treating pain.

D. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws

104. Drug companies' promotional activity can be branded or unbranded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications.

105. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to assess accurately the risks and benefits of drugs for their patients.

106. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places further restrictions on branded marketing. It prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular." "Labeling" includes more than the drug's physical label; it also includes "all … other written, printed, or graphic matter … accompanying" the drug, including promotional material. The term "accompanying" is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug. Thus, the Manufacturer Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

107. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

108. For example, Defendant Purdue made many purposeful misstatements in branded materials in the early 2000s about the safety and efficacy of its first opioid drug,

OxyContin in *branded* marketing materials. These false misrepresentations resulted in criminal charges against Purdue and a resulting settlement of criminal and civil charges for misbranding OxyContin and an agreement to pay the United States government $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct.

109. This kind of penalty, however, can only be levied over misrepresentations in *branded* marketing materials, misrepresentations specific to a particular drug.

110. Defendants' scheme, however, got around federal regulation and the federal criminal and civil law violations that Purdue had run afoul of in the early 2000s by turning to *unbranded* materials, where Defendants could make the same false statements but evade punishment by making these statements about opioids as a whole, not about specific branded opioid drugs.

111. Through the Manufacturer Defendants' sophisticated marketing scheme outlined below, Defendants were able to create unbranded marketing materials that appeared scientifically based and the subject of independent medical judgment, but were actually a front for Defendants who were manufacturing and selling these addictive and unsafe drugs.

112. The Manufacturer Defendants were able to take advantage of this seemingly legitimate unbranded marketing information to implement a persuasive campaign targeted at changing prescribing practices by raising physician and public awareness of purported evidence that opioids could safely and efficaciously treat chronic or long-term pain.

113. In other words, the Manufacturer Defendants disseminated false, misleading, imbalanced, and unsupported statements through a campaign utilizing these unregulated unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids

generally that were false and misleading to sell their specific drugs without running afoul of the laws relating to branded marketing materials.

114. By acting through what appeared to be independent third party professional organizations, the Manufacturer Defendants designed and were able to give the false appearance that their messages reflected the views of independent specialist third parties.

115. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.

116. As part of their deceptive marketing scheme to change the perception of doctors, particularly general practitioners, regarding the dangers of prescribing opioids for long-term use, Defendants spread and validated their deceptive unbranded messages through the following vehicles ("the Vehicles"): (i) so-called "key opinion leaders" (*i.e.*, physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who were paid by Defendants and who wrote favorable journal articles and delivered supportive CMEs as if they were independent medical professionals; (ii) a body of biased and unsupported scientific "literature" funded by Defendants and distributed by the KOLs and Front Groups; (iii) "treatment guidelines" distributed by the Front Groups; (iv) CMEs funded by the Defendants where KOLs and Front Groups taught and portrayed opioids as safe and effective for treatment of chronic pain and distributed Defendants' false and deceptive message; and (v) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both

directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

117. The Manufacturer Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent and credible professional organizations. Through unbranded materials and through the Vehicles, Defendants presented doctors and the public with information and instructions concerning opioids generally that were false and misleading.

118. Even where such unbranded messages were created by the Vehicles themselves, Defendants adopted these messages as their own and distributed them to the medical community and the public by citing to, editing, approving, and distributing such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. In addition, and as described herein, Defendants' sales representatives distributed third-party and unbranded marketing material to Defendants' target audience that was deceptive and false.

119. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Vehicles, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their false and deceptive messages and acted in concert with the Vehicles to fraudulently promote the use of opioids for the treatment of chronic pain.

120. The unbranded marketing materials that Defendants assisted in funding, creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

i. Manufacturer Defendants' KOLs

121. To create the false impression that the opioids they were selling were safe and effective for long term use, the Manufacturer Defendants needed medical

professionals to publicly endorse this view and aggressively promote the use of opioids to treat chronic pain.

122. So the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by Defendants because they favored the aggressive treatment of chronic pain with opioids. As set forth herein and as depicted in Exhibit A, pro-opioid doctors like Drs. Portenoy, Webster, Fine, and Fishman have been at the hub of Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals supported the notion that opioids were safe and efficacious for long-term use.

123. Although these KOLs were funded by the Manufacturer Defendants, this funding went undisclosed and the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

124. As the Manufacturer Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

125. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, Defendants were able to exert control of each of these modalities through which doctors receive their information.

126. In return for their pro-opioid advocacy, Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, as depicted in Exhibit A, Defendant KOL Dr. Webster has received funding from Endo, Purdue, and Cephalon. KOL Dr. Fine has received funding from Janssen, Cephalon, Endo and Purdue.

127. Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of Defendants' agenda. Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, Defendants kept these KOLs well-funded to enable them to push Defendants' deceptive message out to the medical community.

128. Once Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting Defendants' false position that opioids were safe and effective for treatment of chronic pain, Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. Defendants cited to, distributed, and marketed these "studies" and "articles" by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

129. In their promotion of the use of opioids to treat chronic pain, Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and Defendants.

ii. The Manufacturer Defendants' Corruption of Scientific Literature

130. Rather than actually test the safety and efficacy of opioids for long-term use, the Manufacturer Defendants led physicians, patients, and health care payors to believe

that such tests had already been done. As set forth herein, and as depicted in Exhibit A, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

131. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

132. The Manufacturer Defendants' plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants.

133. In these materials, the Manufacturer Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

134. The Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Defendants knew that the articles distorted the significance or meaning of the underlying study.

135. Most infamously, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that made it appear that the item reported the results of a peer- reviewed study. Endo cited the same item in two CME programs that it sponsored. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids.

136. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor,

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when the Manufacturer Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

137. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has by Defendants.

138. The Manufacturer Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants – often with the help of third-party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

139. The Manufacturer Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal obligations.

140. The strategy was intended to, and did, fraudulently co-opt well-intentioned physicians into believing opioids were safe and efficacious for long term use and distort physician prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

iii. The Manufacturer Defendants' Misuse of Treatment Guidelines

141. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain.

Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. The Federation of State Medical Boards

142. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

143. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

144. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

145. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Mecklenburg County.

146. The 2007 publication Responsible Opioid Prescribing was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The

FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications."

147. The Manufacturer Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

b. American Academy of Pain Medicine/American Pain Society Guidelines

148. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[29] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

149. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21

[29] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997). Available at http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (as viewed August 18, 2017).

panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

150. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in Mecklenburg County during the relevant time period, and were and are available online.

151. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines.

c. Guidelines that Did Not Receive Defendants' Support

152. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

153. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of

improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[30]

154. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[31]

155. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[32]

156. The Manufacturer Defendants not only disregarded or tried to discredit such statements, but they used their well-funded and coordinated marketing campaign described herein to drown-out any contradicting message.

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[30] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[31] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

[32] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). https://www.mirecc.va.gov/docs/visn6/CPG_Management_Opioid_Tx_Chronic_Pain_May10.pdf (accessed August 18, 2017).

iv. The Manufacturer Defendants' Misuse of CMEs

157. Now that the Manufacturer Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

158. One way the Manufacturer Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses ("CMEs").

159. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

160. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

161. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

162. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[33]

163. Physicians treating residents and employees of Mecklenburg County attended or reviewed Defendants' sponsored CMEs during the relevant time period and were misled by them.

164. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

v. Defendants' Misuse of Patient Education Materials and Front Groups

165. The Manufacturer Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but it targeted patients who experience chronic pain.

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[33] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

166. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[34] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[35] Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

167. The Manufacturer Defendants entered into arrangements with numerous Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

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[34] Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

[35] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

a. American Pain Foundation

168. The most prominent of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Purdue provided $1.7 million in funding during a time when sales of its OxyContin were skyrocketing.

169. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including the County's residents.

170. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

171. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients.

172. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.

173. The close relationship between APF and Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

174. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[36]

b. The American Academy of Pain Medicine

175. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

176. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

177. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Fine and Dr. Webster. Dr. Webster was elected president of AAPM while under a DEA investigation. Another past AAPM

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[36] American Pain Foundation Website. Available at http://www.painfoundation.org (accessed August 17, 2017).

president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."[37]

178. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

179. Like the KOLs, these Front Groups began to publish literature designed to give the medical community the false impression that prescribing opioids for long term use had been studied and found to be safe and efficacious when nothing of the kind had occurred.

180. The literature published by these Front Groups of course failed to disclose the groups' ties to the Defendants and the pharmaceutical industry.

vi. Defendants' Misuse of Sales Representatives and Physician Relationships

181. The Manufacturer Defendants' sales representatives executed carefully crafted marketing tactics, developed by the highest rungs of their corporate leaders, on how to secure audiences with physicians to pitch opioids and how to make sure physicians and their patients reviewed unbranded marketing materials and considered concepts developed in those materials. Defendants' sales representatives also distributed third-party marketing material to Defendants' target audience that was deceptive.

182. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Mecklenburg County.

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[37] *Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine*, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed August 18, 2017).

By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

183. The Manufacturer Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States and North Carolina, including doctors in Mecklenburg County.

184. The Manufacturer Defendants devoted massive resources to these direct sales contacts with prescribers. For example, in 2014, the industry collectively spent $168 million on detailing opioids to physicians nationwide. Collectively, Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe. The Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more of the Defendants' drugs.

185. The Manufacturer Defendants directed the dissemination of the misstatements described herein to North Carolina patients and prescribers through the Front Groups, KOLS, and publications described above, as well as through each of their substantial sales forces and through advertisements in prominent medical journals. The

deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the safety and efficacy of opioids for long-term use and was again used to shift the prescribing medical community's mindset regarding opioids for chronic pain conditions.

E. Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

186. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain.

187. Despite the devastation that opioids have now wreaked on communities across the United States and in North Carolina, however, Defendants have never retracted any of their false statements and misrepresentations and are still today selling opioids in enormous quantities as safe to treat chronic pain conditions and for long- term use.

188. The Manufacturer Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including to Mecklenburg County prescribers and patients and continue to be disseminated and have never been amended or retracted.

189. One Vehicle for Defendants' marketing collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe

described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

190. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from Defendants.

191. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[38] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

F. Defendants' Misrepresentations

192. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Mecklenburg County. These

[38] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

promotional messages were intended to and did encourage patients to ask for doctors to prescribe, and payors to pay for chronic opioid therapy.

193. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Defendants did not disclose to prescribers, patients or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors treating Mecklenburg County residents began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

194. Drug company marketing materially impacts doctors' prescribing behavior.[39] Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs.

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[39] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

195. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[40] These results are directly due to Defendants' fraudulent marketing campaign.

196. As described in detail below, Defendants:

- misrepresented the truth about how opioids lead to addiction;
- misrepresented that opioids improve function;
- misrepresented that addiction risk can be managed;
- misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- falsely claimed that withdrawal is simply managed;
- misrepresented that increased doses pose no significant additional risks;
- falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

197. Defendants' misrepresentations were aimed at doctors, patients, the public, and payors.

198. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community and the public the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.[41]

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[40] Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

[41] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

i. Defendants, acting individually and collectively, misrepresented the truth about how opioids lead to addiction.

199. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, the public, and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients – thereby enriching Defendants.

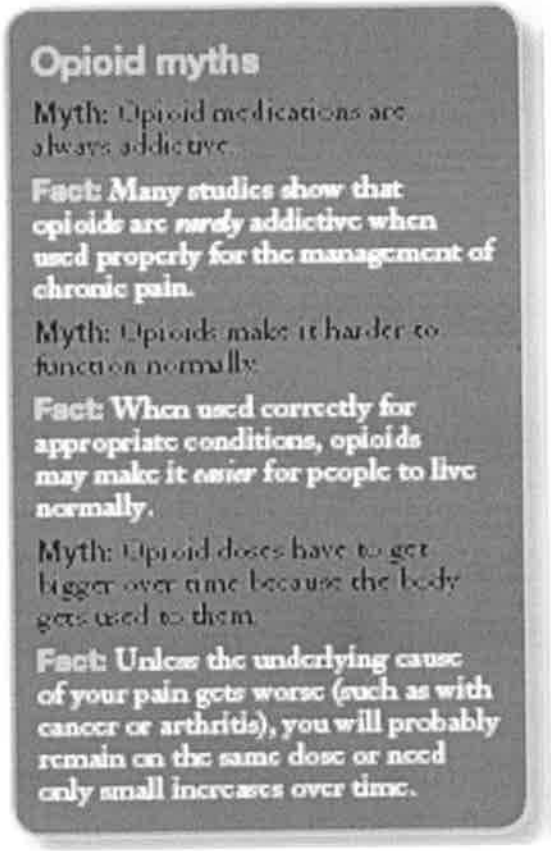
200. Each of the Defendants claimed that the potential for addiction from its drug was relatively small or non-existent, even though there was no scientific evidence to support those claims.

201. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

202. For another example, Endo sponsored a website, *painknowledge.com*, through APF, which claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use will not become problematic.

203. For another example, Endo distributed a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for *genuine* pain will not become addicted, which is unsupported and untrue.

204. For another example, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described as a "myth" the fact that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use is unlikely to lead to addiction, which is untrue.

205. The guide states as a "fact" that "Many studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

206. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with

opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

207. For another example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[42] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

208. For another example, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and featuring doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[43]

209. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who relieved their pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to*

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[42] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[43] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed August 18, 2017).

Understanding Pain & Its Management, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction."[44]

210. *Let's Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients . . . This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

ii. Defendants, acting individually and collectively, misrepresented that opioids improve function

211. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

212. Although opioids may initially improve patients' function by providing pain relief in the short term, there exist no controlled studies of the use of opioids beyond 12 weeks and no evidence that opioids improve patients' function in the long-term. Indeed, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be

[44] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

disabled and unable to work.[45] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

213. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[46]

214. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo, and Purdue, supported by APF and AAPM, and written by Dr. Fishman and with Dr. Fine on the Board of Advisors, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."[47]

215. Cephalon and Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (*e.g.*, aspirin or ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently available online.

216. Endo sponsored a website, *painknowledge.com*, through the APF, which claimed in 2009 that with opioids, "your level of function should improve; you may find

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[45] Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

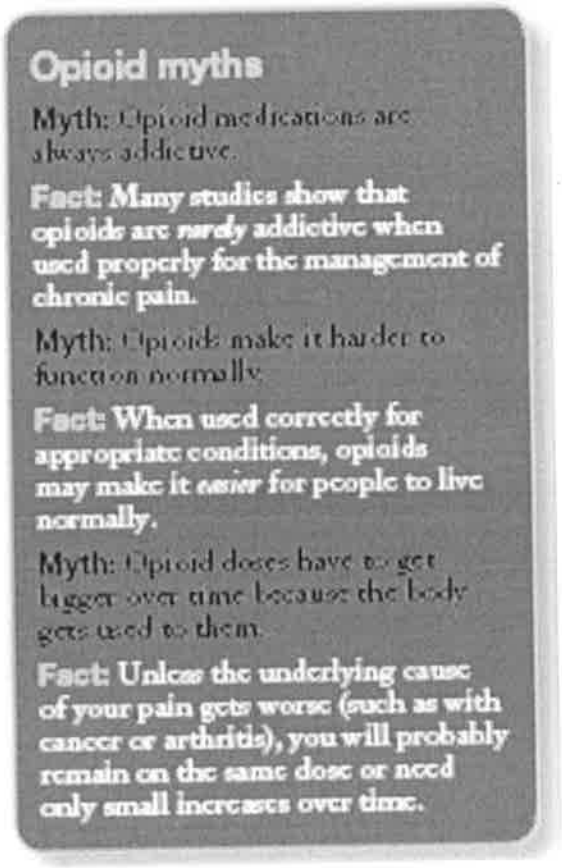
[46] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA 21-260 (March 24, 2008).

[47] *Responsible Opioid Prescribing*, (available at https://archive.org/stream/279187-responsible-opioid-prescribing-info/279187-responsible-opioid-prescribing-info_djvu.txt (accessed August 31, 2017).

you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

217. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

218. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.



Opioid myths

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Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

219. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

220. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients, with the implication these studies presented claims of long-term improvement.

> Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:
>
> - Daily function
> - Psychological health
> - Overall health-related quality of life for people with chronic pain [12]

The sole reference for the functional improvement claim (i) noted the absence of long-term studies and (ii) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

221. Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning."

iii. Defendants, acting individually and collectively, misrepresented that addiction risk can be effectively managed

222. Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. None of the Defendants have withdrawn, amended or retracted their false statements or attempted to reeducate the medical community that what they originally taught was false and misleading.

223. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have come to admit that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

224. There are three fundamental flaws in Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that

patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

225. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[48] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, even when well meaning, but doctors were misled to employ them.[49]

226. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011-2012 narcotic prescription data of the type regularly used

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[48] The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

[49] M. Von Korff, et al., *Long-term opioid therapy reconsidered*, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

by Defendants to market their drugs, that, of the more than half a million prescribers of opioids during that time period, only 385 were identified as pain specialists.[50]

227. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring – with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a "heads you lose; tails you lose" outcome for patients – all of whom are subjected to an unacceptable risk of addition – and for payors, including Plaintiff.

228. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

229. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Defendant Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

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[50] Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

230. Purdue sponsored a 2011 webinar taught by Defendant Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

iv. Defendants, acting individually and collectively, misled physicians, patients, and payors through the use of misleading pseudowords like "pseudoaddiction."

231. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe even more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by Dr. Portenoy. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

232. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence. Defendants have never withdrawn, amended or retracted these representations.

233. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007) written by Dr. Fishman and with Dr. Fine on the Board of Advisors, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

234. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did

Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[51]

235. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

v. Defendants, acting individually and collectively, claimed withdrawal is simply managed.

236. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – an adverse effect that also makes it less likely that patients will be able to stop using the drugs.

237. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal

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[51] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

238. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days – when it is successful at all.[52]

239. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

vi. Defendants, acting individually and collectively, misrepresented that increased doses pose no significant additional risks.

240. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

241. In materials Defendants produced, sponsored or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

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[52] *See* Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

242. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[53]

243. Cephalon sponsored a CME written by KOL Defendant Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

244. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

245. Endo distributed a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased . . . You won't 'run out' of pain relief."

246. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

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[53] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004).

247. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

vii. Defendants, acting individually and collectively, deceptively omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

248. In materials they produced, sponsored or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

249. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[54] hormonal dysfunction;[55] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[56] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are

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[54] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[55] H.W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) J. Pain 377-84 (2001).

[56] *See* Bernhard M. Kuschel, *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, Eur. J. Pub. H. (July 31, 2014).

used to treat post-traumatic stress disorder and anxiety, which often accompany chronic pain symptoms.[57]

250. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[58] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

251. Endo sponsored a website, *painknowledge.com*, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

252. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which omits warnings of the risk of potentially fatal interactions between opioids and benzodiazepines, which are commonly prescribed to veterans suffering from post-traumatic stress disorder.

253. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of

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[57] Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47 (2012).
[58] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004).

visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[59]

G. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded, and Dangerous and Would Harm Plaintiff

254. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

255. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

256. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in

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[59] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51(*10*) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

H. Defendants Fraudulently Concealed their Misrepresentations

257. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

258. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain.

259. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

260. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of

Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

261. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

262. Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

263. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

I. Defendants Entered into and Engaged in a Civil Conspiracy

264. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiracy.

265. Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

266. This network is interconnected and interrelated, as illustrated by Exhibit A, which is incorporated herein, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded

collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

267. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

268. As set forth herein and in Exhibit A, Defendants also conspired with various KOLs and Front Groups to commit unlawful acts or lawful acts in an unlawful manner. Defendants knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants agreed with various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and Defendants—along with the Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

269. By engaging in the conduct described in this Complaint, Defendants agreed with Front Groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of their agreements with one another and Front Groups, Defendants provided support for Front Group's deceptive statements promoting opioids and Front Groups used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Defendants' drug sales, as well as other opioid makers' sales.

270. Each of the participants in the conspiracies described herein and in Exhibit A was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to the public, patients

and prescribers in North Carolina in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

271. As outlined in greater detail herein and as illustrated in Exhibit A, opioid makers Cephalon, Endo, Janssen, along with Defendants Purdue and Defendant KOLs played an active role in determining the substance of the misleading messages issued by Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers. Defendants exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

272. Defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. violating the Unfair and Deceptive Trade Practices Act;

b. perpetrating a public nuisance;

c. committing common law unjust enrichment; and

d. perpetuating a fraud.

273. By reason of the foregoing, the County was injured and continues to be injured in that Defendants' ongoing concerted actions in marketing opioids caused doctors and other health care providers to prescribe and the County to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendant caused and are responsible for those costs and claims. In addition, the County has suffered additional damages for the costs of providing and using opioids long-term

to treat chronic pain because its human services, social services, court services, law enforcement services, the office of the coroner/medical examiner and health services, including hospital, emergency and ambulatory services, have all been severely impacted by the crisis.

J. The Distributor Defendants Failed to Maintain Effective Controls Over the Distribution of Prescription Opioids

274. The Distributor Defendants are wholesale distributors of pharmaceuticals who operate within the County and distribute prescription opioids to pharmacies and other retail outlets within the County from which end users obtain opioids by prescription (together, "retailers").

275. Distributor Defendants are considered the "Big 3" of pharmaceutical distributors and together dominate 85% of the market share for the distribution of prescription opioids. Each of the Distributor Defendants is a Fortune 500 corporation listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. Each has been investigated and/or fined by the DEA or other governmental entities for the failure to report suspicious orders.

276. At all relevant times, the Distributor Defendants purchased opioids from manufacturers, including the Manufacturing Defendants, and sold them to retailers throughout the County.

277. Most or nearly all of the prescription opioids that were sold to retailers within the County were purchased from the Distributor Defendants.

278. Under the Federal Controlled Substances Act ("CSA") and under North Carolina state statute and regulations, the Distributor Defendants are required to keep and maintain detailed records of scheduled narcotics that they sell and deliver to pharmacies and other outlets. The level of detail required by these laws is intended to flag for both the distributor and government enforcement agencies "suspicious orders" that suggest that controlled substances, such as prescription opioids, are being

oversupplied and potentially diverted from proper medical use to an illicit market for illegal demand and consumption.

279. Distributors are further required under both state and federal law to report suspicious orders of controlled substances like prescription opioids. The purpose of this reporting requirement is to alert regulatory and law enforcement officials where it appears prescription pharmaceuticals are being diverted for illegal use.

280. Both the state and federal laws require that distributors, including the Distributor Defendants, maintain records of sufficient detail, and with sufficient knowledge of the lawful market for controlled substances including prescription opioids such that suspicious orders will be apparent and can be identified by them.

281. The Distributor Defendants are also members of the Healthcare Distribution Management Association ("HDMA"). The HDMA created "Industry Compliance Guidelines" which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

282. Together, these laws and industry guidelines make clear that the Distributor Defendants possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

283. Further, these laws and industry guidelines make clear that the Distributor Defendants have the duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

284. In fact, Distributor Defendants were repeatedly instructed by regulators of their duties. For example, the DEA has provided briefings to each of the Defendant Distributors and conducted a variety of conferences regarding their duties and the likely and foreseeable risks that follow the failure to properly control the distribution of controlled substances such as prescription opioids.

285. The DEA sent a letter to each of the Defendant Distributors on September 26, 2006, that expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

286. The DEA sent a second letter to each of the Defendant Distributors on December 27, 2007. This letter reminded the Defendant Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective

> controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

287. Thus, the Distributors are, and are expected to be, a key link in the chain of pharmaceutical distribution within a "closed system" intended to make sure that prescription drugs are sold solely for use pursuant to prescription, and not to be diverted for sale and use for illegal, non-medical purposes. Distributors have the duty and are expected to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as the illegal distribution of controlled substances has a substantial and detrimental effect on the public health and general welfare.

288. The state and federal requirements and industry guidelines identified herein, individually and together, make clear that, because of Distributors' position within the distribution chain and their required level of knowledge, skill, and sophistication, the Distributors have a duty to maintain effective controls over controlled substances such as prescription opioids to prevent their abuse and diversion for illicit purposes.

289. The Distributor Defendants were each on notice that the prescription opioids they distributed were susceptible to overuse, misuse, and diversion for illegal purposes, and otherwise sought for illegal, unhealthy and dangerous purposes.

290. The Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and the North Carolina Department of Health and Human Services.

291. Because Distributor Defendants have the legal obligation to maintain a system that would reveal suspicious orders, the Distributors are in a unique position to

inspect, report, or otherwise limit the distribution and flow of prescription opioids into the County to prevent the oversupply and diversion of these drugs to the illicit market.

292. Accordingly, the Distributor Defendants owe a duty to detect, investigate, report, and refuse to fill suspicious orders of prescription opioids, and to maintain effective controls to prevent the oversupply into the County and the diversion to the illicit market.

293. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids into the illicit market, contributing to overuse, misuse, addiction, and overdoses within the County and the damages and harms caused to the community thereby.

294. Despite the Distributor Defendants' duties, and the foreseeable harm resulting from a breach of these duties, the Distributor Defendants have displayed a continuing pattern of fulfilling and failing to report suspicious orders and continuing to provide an oversupply of prescription opioids.

295. For example, in 2008, McKesson paid a $13.25 million federal fine to settle claims regarding suspicious orders from internet pharmacies.[60]

296. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

297. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."[61]

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[60] http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state (accessed May 30, 2017).

[61] https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (accessed May 30, 2017).

298. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[62]

299. Similarly, in 2008, Defendant Cardinal paid a $34 million federal penalty to resolve allegations that it failed to report suspicious opioid orders.[63]

300. Despite this past penalty, in 2017, it was announced that defendant Cardinal agreed to a $44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.[64]

301. Likewise, Defendant AmerisourceBergen faced a criminal inquiry "into its oversight of painkiller sales" in 2012.[65] They have paid out fines for similar claims to the state of West Virginia.

302. Despite their duties, and despite the charges, fines, and penalties brought against the Distributor Defendants in the past, the Distributor Defendants continue to provide an oversupply of prescription opioids within the County and fail to report suspicious orders or prevent the diversion of prescription opioids to the illicit market. The Distributor Defendants knew or should have known that they were oversupplying prescription opioid medications within the County that far exceeded the amounts needed for legitimate medical use and that were likely resulting in diversion of the drugs into an illicit market.

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[62] *Id.*

[63] https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0 (access May 30, 2017).

[64] https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.7049c4431465 (accessed on May 30, 2017).

[65] http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html (accessed on May 30, 2017).

303. The Distributor Defendants filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency within the County and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into the County for improper sale and use.

304. Among other things, the Distributor Defendants' continuing oversupply of prescription opioids has caused or has been a substantial causal factor contributing to the prevalence of illegal pill mills within the County that have sold hundreds of millions of dollars' worth of prescription opioids unlawfully.

305. Indeed, rather than satisfy their duties not to oversupply prescription opioids within the County, to maintain effective controls over the supply and distribution of prescription opioids, and to identify, report, investigate and halt suspicious orders, the Distributor Defendants affirmatively sought and obtained statutory changes and a reduction in federal enforcement efforts that enabled the Distributors to continue breaching these duties with relative impunity.[66]

306. The Distributor Defendants' oversupply of prescription opioids within the County and their failure to monitor, detect, investigate, refuse to fill, and report suspicious orders is a direct and proximate cause of, and/or substantial factor contributing to, the diversion of millions of doses of prescription opioids into the illicit market for purposes other than legitimate medical use. The Distributor Defendants' conduct caused or contributed substantially to the very harm that the state and federal

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[66] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic- grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea- enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

laws and industry guidelines were intended to prevent, namely, the diversion of prescription opioids for illegitimate and/or nonmedical purposes.

FIRST CAUSE OF ACTION
UNFAIR AND DECEPTIVE TRADE PRACTICES ACT ("UDTPA")
VIOLATIONS OF N.C. GEN. STAT. § 75-1.1, *et seq*,
(AGAINST THE MANUFACTURER DEFENDANTS)

307. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

308. The Manufacturer Defendants, among other things, manufacture, distribute, promote, and/or sell opioids.

309. As alleged above, each of the Manufacturer Defendants violated N.C. Gen. Stat. 75-1.1 by engaging in "unfair and deceptive acts or practices in or affecting commerce" by making representations to the public that were untrue, deceptive or misleading with intent to sell or to induce sales of opioids.

310. These untrue, deceptive, or misleading statements included, but were not limited to:

a. misrepresenting the truth about how opioids lead to addiction;

b. misrepresenting that opioids improve function;

c. misrepresenting that addiction risk can be managed;

d. misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"

e. falsely claiming that withdrawal is simply managed;

f. misrepresenting that increased doses pose no significant additional risks;

g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

311. Defendants, through their conduct up to and including the present day, continue to make statements and representations to the public that are untrue, deceptive

or misleading with intent to sell or to induce sales of opioids. Manufacturer Defendants have not pulled their opioid products from the market, acknowledged the very real dangers of addiction and abuse, even if the opioids are taken as prescribed, or acknowledged that opioids are inappropriate for long-term pain management. Instead, each of the Manufacturer Defendants continue to offer their opioid products for long-term pain management and have taken the position that their opioid products are not dangerous if taken as prescribed. The Manufacturer Defendants have also taken the position that addiction and overdoses are the result of individual choice to misuse or abuse opioids, not the dangers inherent in their product, thereby continuing to fuel the crisis.

312. Plaintiff seeks injunctive relief as well as pecuniary damages and treble damages because of the Manufacturer Defendants' violations in an amount to be determined at trial.

SECOND CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST THE MANUFACTURER DEFENDANTS)

313. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

314. Each Manufacturer Defendant's conduct, both individually and collectively, in creating and then maintaining the opioid crises constitutes a public nuisance. The conduct of each Manufacturer Defendant involves a significant interference with the public health, the public safety, the public peace, and the public comfort. Each Manufacturer Defendant's conduct giving rise to the opioid crisis is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has reason to know, has a significant effect on the entire community.

315. Each Manufacturer Defendant's interference with the public health, the public safety, the public peace, and the public comfort resulted significant harm to the

County. The significant harm that each Manufacturer Defendant has caused the community and the public by its conduct in creating and then maintaining the opioid crisis for its own individual profit is substantially offensive and intolerable.

316. Each Manufacturer Defendant intentionally caused the public nuisance complained of herein. The conduct of each Manufacturer Defendant, either individually or collectively, was a substantial factor in producing and then maintaining the opioid crisis that is a significant interference with the public health, the public safety, the public peace, and the public comfort. Further, each Manufacturer Defendant acted either knowing, or was substantially certain, that its false, deceptive and misleading information and statements regarding the dangers, addictive nature and abuse potential of their opioid products would result in the public nuisance and significant harm complained of herein.

317. Each Manufacturer Defendant was also negligent as each engaged in the conduct complained of herein to create an unreasonable risk of the public nuisance complained of herein, and then failed to abate the public nuisance they created. Moreover, each Defendant's negligent conduct, both individually and collectively, was a cause of the public nuisance complained of herein.

318. Each Manufacturer Defendant's conduct in causing the public nuisance complained of herein was unreasonable and the gravity of the harm caused far outweighs any utility of the Defendant's conduct.

319. Each Manufacturer Defendant's conduct damaged, and continues to damage, the County in an amount to be determined at trial.

THIRD CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST THE DISTRIBUTOR DEFENDANTS)

320. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

321. Each Distributor Defendant's conduct, both individually and collectively, in creating and then maintaining the opioid crises constitutes a public nuisance. The conduct of each Distributor Defendant involves a significant interference with the public health, the public safety, the public peace, and the public comfort. Each Distributor Defendant's conduct giving rise to the opioid crisis is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has reason to know, has a significant effect on the entire community.

322. Each Distributor Defendant's interference with the public health, the public safety, the public peace, and the public comfort resulted significant harm to the County. The significant harm that each Distributor Defendant has caused the community and the public by its conduct in creating and then maintaining the opioid crisis for its own individual profit is substantially offensive and intolerable.

323. Each Distributor Defendant intentionally caused the public nuisance complained of herein. The conduct of each Distributor Defendant, either individually or collectively, was a substantial factor in producing and then maintaining the opioid crisis that is a significant interference with the public health, the public safety, the public peace, and the public comfort. Further, each Distributor Defendant acted either knowing, or was substantially certain, that its failure to maintain effective controls over the distribution of prescription opioids, including by oversupplying prescription opioids and by fulfilling and failing to identify or report suspicious orders, would result in the public nuisance and significant harm complained of herein.

324. Each Distributor Defendant was also negligent as each engaged in the conduct complained of herein to create an unreasonable risk of the public nuisance complained of herein, and then failed to abate the public nuisance they created. Moreover, each Distributor Defendant's negligent conduct, both individually and collectively, was a cause of the public nuisance complained of herein.

325. Each Distributor Defendant's conduct in causing the public nuisance complained of herein was unreasonable and the gravity of the harm caused far outweighs any utility of the Distributor Defendant's conduct.

326. Each Distributor Defendant's conduct damaged, and continues to damage, the County in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

327. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

328. Distributor Defendants have a duty to exercise reasonable care in the distribution of prescription opioids.

329. With respect to the Distributor Defendants, reasonable care includes the duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to maintain effective controls over the distribution of prescription opioids, including to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, and to identify, report, and refuse to fill suspicious orders.

330. Distributor Defendants, acting individually, together, and in concert with others, were negligent both generally and in not utilizing their specialized and sophisticated knowledge, information, skill, and understanding to maintain effective controls over the distribution of prescription opioids, including to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, and to identify, report, and refuse to fill suspicious orders.

331. Distributor Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the improper or unlawful acts of third parties.

332. As a proximate result of the Distributor Defendants breach of their duties of care, Distributor Defendants and its agents damaged and continues to damage the County in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

333. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

334. Defendants unjustly retained a benefit to the County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

335. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at the County's expense. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the County lacks a remedy provided by law.

336. Defendants conduct damaged and continues to damage the County in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
COMMON LAW FRAUD
(AGAINST THE MANUFACTURER DEFENDANTS)

337. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

338. The Manufacturer Defendants conduct constitutes fraud.

339. The Manufacturer Defendants, individually and acting through their employees and agents, and in concert with each other, misrepresented material facts with

regards to the use of opioids to treat chronic pain through various means including but not limited to:

a. Creating and/ or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the ability of opioids to improve function long-term;

b. Creating and/or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the ability of opioids to improve quality of life while concealing contrary data;

c. Creating and/or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain, including known rates of abuse and addiction and lack of validation for long-term efficacy;

d. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction, even for high-risk patients;

e. Disseminating misleading statements concealing the true risk of addiction in the elderly;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an imbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Falsely claiming that withdrawal is simply managed; and

h. Misrepresenting that increased doses of opioids pose no significant additional risks.

340. The Manufacturer Defendants' false representations and concealments were made with the intent to deceive the County; as well as County consumers who used or paid for opioids for chronic pain; County physicians who prescribed opioids to consumers to treat chronic pain; and County payors, who purchased, or covered the purchase of, opioids for chronic pain.

341. The Manufacturer Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic pain.

342. The Manufacturer Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[67]

343. The Manufacturer Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use in managed settings where the risk of addiction and other adverse outcomes was significantly minimized.

344. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, the Manufacturer Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches, and did so through misrepresentations including those listed above.

345. The Manufacturer Defendants' misrepresentations saturated the market, were promulgated in part by third parties positioned as experts, and extended to almost every available source of information including prescribing guidelines, CMEs, patient educational materials, and journal publications.

346. Plaintiff did reasonably rely on these false representations made by Manufacturer Defendants and third parties in their control.

347. But for these false representations and concealments of material fact, Plaintiff would not have purchased or covered the purchase of opioids for chronic pain.

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[67] *See*, e.g., Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

But for these false representations, there would not have been a massive opioid addiction and overdose epidemic that has strained the Plaintiff's budgets.

348. The Manufacturer Defendants' conduct damaged and continues to damage the County in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION
CIVIL CONSPIRACY
(AGAINST THE MANUFACTURER DEFENDANTS)

349. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

350. The Manufacturer Defendants formed and operated a conspiracy to accomplish an unlawful purpose or to accomplish their mutual goal of increasing each Manufacturer Defendants' sales of their opioid products by unlawful means.

351. The conspiracy's unlawful purpose was to create a false and dangerous perception amongst both physicians and the public that the risks of addiction and the abuse potential of Manufacturer Defendants' opioid products was negligible if taken as prescribed to treat long-term pain, conduct that is contrary to the Unfair and Deceptive Trade Practices Act, constitutes a fraud, and created a public nuisance.

352. In addition, the conspiracy's mutual goal was to increase each Manufacturer Defendant's sales by spreading untrue, deceptive or misleading information regarding the danger, risk of addiction, and abuse potential of their opioid products, conduct that is at a minimum contrary to the Unfair and Deceptive Trade Practices Act, constitutes a fraud, and created a public nuisance.

353. The conspiracy amongst the Manufacturer Defendants is established by all of the acts and events, viewed as a whole, which as set forth herein and in Exhibit A show how Manufacturer Defendants cooperated toward the attainment of the common goals of their conspiracy. This includes, but is not limited to, knowingly and voluntarily agreeing to engage in unfair and deceptive practices to promote the use of opioids for the

treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers.

354. Defendants enlisted various KOLs and Front Groups as part of their conspiracy to make and disseminate these statements to further their common strategy to increase opioid sales.

355. Products of the conspiracy include but are not limited to publications, CMEs, and websites that deceptively promote the risks, benefits, and superiority of opioid therapy, such as: The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF), *Responsible Opioid Prescribing* (Purdue, Cephalon, Endo, APF, AAPM, and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS).

356. As outlined in greater detail herein and in Exhibit A, the Manufacturer Defendants played an active role in determining the substance of the misleading messages issued by Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements.

357. The Manufacturer Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance for distribution.

358. Indeed, even now and having caused the opioid crises complained of herein, the Manufacturer Defendants have provided a unified front to deny their opioid products are dangerous to treat long-term pain even if taken as prescribed and instead blame the addiction and abuse on individual misuse and individual choice. Despite evidence to the contrary, each Manufacturer Defendant uniformly refuses to acknowledge the very real dangers of addiction and abuse, even if the opioids are taken

as prescribed, or acknowledged that opioids are inappropriate for long-term pain management, thereby providing further evidence of their conspiracy.

359. The result is an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers.

360. The Manufacturer Defendants' ongoing civil conspiracy damaged and continues to damage the County in an amount to be determined at trial.

PUNITIVE DAMAGES

361. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

362. By engaging in the above-described unfair acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm.

363. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the community, and an award of punitive damages is appropriate, as punishment and a deterrence.

364. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment against Defendants, jointly and severally, awarding Plaintiff:

1. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
2. costs and attorney fees;
3. a declaratory judgment requiring Defendants to abate the public nuisance;
4. punitive damages;
5. interest, costs, and disbursements; and
6. such other and further relief as this Court deems just and proper.

Jury Demand

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury on all issues so triable under the law.

Dated: February 8, 2018.

By: /s/ Janet Ward Black

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*application for admission forthcoming